PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER FOR APPEAL BRIEF

Applicant: Roger P. Jackson

Serial No.: 10/789,134 Date: December 6, 2006

Filed: February 27, 2004 Group Art Unit: 3733

Exam: Mary C. Hoffman

For: ORTHOPEDIC IMPLANT ROD REDUCTION TOOL SET AND METHOD

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Kansas City, Missouri

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant submitted an Appeal Brief in this application on October 16, 2006. Based upon that submission the Patent Office issued a notice on November 6, 2006 that the Brief failed to include a concise explanation of each of the independent claims on appeal.

Consequently, submitted herewith is a replacement Appeal Brief to which the noted subject matter has been added.

The fee for submitting the Brief has previously been paid and, therefore, there is no additional fee believed due. However, if an additional fee is required, kindly charge deposit account 50-1253.

Respectfully Submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
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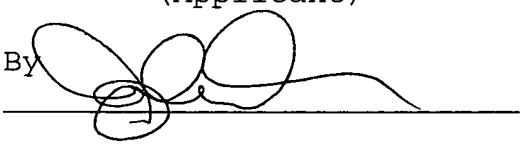
December 6, 2006

Roger P. Jackson
(Applicant)

By 

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ATTENTION: Board of Patent Appeals and Interferences

APPELLANT'S BRIEF

This brief is filed in support of the Notice of Appeal in this application which was mailed on August 11, 2006.

The fees required under 41.2(b)(2) are submitted herewith.

I REAL PARTY IN INTEREST

The applicant Roger P. Jackson is the real party in interest.

II RELATED APPEALS AND INTERFERENCES

there are no current related appeals or interferences.

III STATUS OF CLAIMS

The status of the claims in this application are:

A. TOTAL NUMBER OF CLAIMS IN APPLICATION: 9

B. STATUS OF ALL OF THE CLAIMS:

1. Claims canceled: NONE
2. Claims withdrawn from consideration but not canceled: 8 and 9
3. Claims pending: 1 through 9
4. Claims allowed: NONE
5. Claims rejected: 1 through 7

C. CLAIMS ON APPEAL: All pending claims

IV STATUS OF AMENDMENTS

An amendment was submitted on August 11, 2006 to correct the dependency of Claim 8 and 9. This amendment has not been entered.

V SUMMARY OF CLAIMED SUBJECT MATTER

CONCISE EXPLANATION OF INDEPENDENT CLAIM 1

A pair of guide tools 9 (paragraphs 36 and 37) for operably guiding a rod 4 into receiving bone screws 6 (process described in paragraph 57). Each of the guide tools 9 has an upwardly extending channel 34 (paragraph 38) to guide the ends of the rods 4. Located at the bottom of each tool 9 is an attachment structure 113 (paragraph 50) for removably attaching to a bone screw 6. Also located in the bottom of each guide tool 9 is a helically wound guide and advancement structure 50 (paragraph 39). The structure 50 is configured so that, when the tool 9 is attached to a respective bone screw 6, a mating guide and advancement structure 76 (paragraph 43) of the bone screw 6 (see Figs 17 and 18) aligns therewith, so that a closure 52 (paragraph 52) with a second guide and advancement structure 125 (paragraph 51) is adapted to be rotated and advanced from the tool 9 to the bone screw 6 under torque and without losing control of the closure 52 while pushing the rod 4 into the bone screw 6.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 2

A pair of guide tools 9 (paragraphs 36 and 37) for operably guiding a rod 4 into receiving bone screws 6 (process described in paragraph 57). Each of the guide tools 9 has a slot 34 (paragraph 38) from the bottom upward to guide the ends of the rods 4. Located at the bottom of each tool 9 is an attachment structure 113 (paragraph 50) for removably attaching to a bone screw 6. Also located in the bottom of each guide tool 9 is a first helically wound guide and advancement structure 50 (paragraph 39). The structure 50 is configured so that, when the tool 9 is attached to a respective bone screw 6, the structure 50 aligns with a second structure 76 (paragraph 43) of the bone screw 6 (see Figs 17 and 18), so that a closure 52 (paragraph 52) with a mating guide and advancement structure 125 (paragraph 51) is adapted to be rotated and advanced from the tool 9 to the bone screw 6 under torque and without losing control of the closure 52, while pushing the rod 4 into the nonintegral bone screw 6.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 3

A pair of guide tools 9 (paragraphs 36 and 37) for operably guiding a rod 4 into receiving bone screws 6 (process described in paragraph 57). Each of the guide tools 9 is non integral with an associated bone screw 6 and has an upwardly extending channel

29 (paragraph 38) to guide the ends of the rods 4. Located at the bottom of each tool 9 is an attachment structure 113 (paragraph 50) for removably attaching to a bone screw 6. Also located in the bottom of each guide tool 9 is a helically wound guide and advancement structure 50 (paragraph 39). The structure 50 is configured so that when the tool 9 is attached to a respective bone screw 6, a mating guide and advancement structure 76 (paragraph 43) of the bone screw 6 (see Figs 17 and 18) aligns therewith, so that a closure 52 (paragraph 52) with a second guide and advancement structure 125 (paragraph 51) is adapted to be rotated and advanced from the tool 9 to the bone screw 6 under torque and without losing control of the closure 52, while pushing the rod 4 into the bone screw 6.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 4

A kit including a pair of guide tools 9 (paragraphs 36 and 37) for operably guiding a rod 4 into receiving bone screws 6 (process described in paragraph 57). Each of the guide tools 9 is non integral with respect to an associated bone screw 6 and has an upwardly extending guide channel 34 (paragraph 38) to guide the ends of the rods 4. Located at the bottom of each tool 9 is an attachment structure 113 (paragraph 50) for removably attaching to a bone screw 6. Also located in the bottom of each

guide tool 9 is a helically wound guide and advancement structure 50 (paragraph 39). The structure 50 is configured so that when the tool 9 is attached to a respective bone screw 6, a mating guide and advancement structure 76 (paragraph 43) of the bone screw 6 (see Figs 17 and 18) aligns therewith, so that a closure 52 (paragraph 52) with a mating guide and advancement structure (paragraph 51) 125 is adapted to be rotated and advanced from the tool 9 to the bone screw 6 under torque and without losing control of the closure 52 while pushing the rod 4 into the bone screw 6. This claim also includes intermediate guide tools 10 (paragraph 45) which have similar structure to the end tools 9 and join with bone screws 6 also. Each intermediate tool 10 has a pass through slot 105 (paragraph 47) for receiving the rod 4 therethrough.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 6

A guide tool 9 (paragraphs 36 and 37) for operably guiding a rod 4 (procedure described in paragraph 57) into a bone screw 6 which are selectively connectable. The guide tool 9 has first guide and advancement structure 113 (paragraph 50) and the bone screw 6 has a pair of spaced upwardly extending arms 74 and 75 (paragraph 43) that include a second guide and advancement structure 76 (paragraph 43). The first and second guide and

advancement structures 113 and 76 align when the tool 9 is joined to the bone screw 6 so as to form a continuous helically wound path (113 and 76 combined, as seen in Figs. 17 and 18) which is adapted to guide a closure 52 (paragraph 52) under rotation from the guide tool 9 to the bone screw 6.

The following is an overview summary of the claimed subject matter. In spinal surgery bone screws 6, hooks and other implants are selectively joined to rods 4 to produce an assemblage that functions as a support structure for the spine of a patient. In typical surgeries, closed headed implants are sometimes used (about 10% of the time) wherein a rod is threaded into a closed head. However, most current surgeries use an open headed implant (here illustrated as bone screw 6)having an open head such as the illustrated head 66 wherein the rod 4 is placed in a rod receiving channel 67 in the head 66 and then the channel 67 is closed by a closure top 52 that also exerts pressure on the rod 4 and locks the rod 4 in place relative to the head 66.

Because the implants 6 are often used to align the vertebrae 18 to which they are joined, the rod 4 and successive receiving channels 67 may not align after the rod 4 is inserted in several bone screws 6 in the spine 17 (as shown in Fig. 13). That is,

the rod 4 may initially be spaced above the implant head 6 in some circumstances. For the closure top 52 to functionally join with the head 66, the advancement structure 125 spare (threads or flange form) of the closure 52 must mate with and rotate into the internal guide and advancement structure 76 in the head 66 so as to be located in and close the channel 67. This process is shown in Figs. 17 and 18.

In previous times, all back surgery of this type was preformed by open incision wherein the surgeon made a large incision and actually had his hands within the back of the patient in contact with the implants and bones or at least could easily grasp the bone screws and rod by hand and tools and draw them together.

While minimally invasive surgery cannot be practiced in all cases, most recent surgery has become minimally invasive to reduce trauma experienced by the patient. In such surgery small surgical openings are made in the patient's back and the bone screws and rods are inserted through these openings (see Fig. 13 for example). Because the bone screws 6 are not readily accessible by the surgeon beneath the skin, it is difficult to manipulate and install the bone screws 6. It is especially

difficult to guide the rod 4 into the receiving channel 67 in the head 66 when one or more of the vertebrae 18 must be moved in order to seat the rod 4 in one or more heads 67 of the bone screws 6 (or hooks).

Consequently, applicant has developed a series of end and intermediate tools 9 and 10 for assisting the surgeon in installing bone screws 6 and hook implants and then joining these implants with a rod 4 using minimally invasive surgery. This process for joining the rod 4 to a series of bone screws is shown in Figs. 13 to 19.

Certain aspects of applicant's guide tools 9 and 10 other than those claimed in the present invention are believed to be patentable and separate applications for patent are filed on those aspects.

The claims of the present application are especially directed to the concept of each of the tools 9 and 10 having an attachment structure (for example attachment structure 55 of tool 9) that allows a surgeon to attach the tool 9 or 10 to a mating attachment structure (as shown a receiver 78) of each implant head 66 prior to insertion of the rod 4 and normally prior to

insertion of the implant into the bone and then detach the tool 9 or 10 after the rod 4 is inserted. Each tool 9 and 10 also has a guide channel (such as combined channels 25, 29 and 34 in guide tool 9)that receives and guides a rod 4 to the implant head 66.

Importantly, each tool 9 and 10 has a guide and advancement structure 50 in tool 9 that aligns with a like structure 76 on the interior of the channel 67 of the head 66, when the tool 9 or 10 mates with the head 66, and allows the closure top 52 to be rotated and advanced from a location above the head 66 (see Fig. 17) and into the head 66 (see Fig. 18) while continuously applying pressure to the rod 4 relative to the bone screw 6, so that the rod 4 and head 66 come into seating engagement with one another (also as seen in Fig 18).

In the manner the tools 9 and 10 can extend through a patient's skin to allow the surgeon to manipulate the bone screw 6 or hook and thereafter while the bone screw 6 or hook remains under control of the tool 9 and 10 to insert the rod 4 and closure 52. The guide and advancement structure 50 on tool 9 and mating structure 76 on the head 66 allows the rod 4 to be urged into the head channel 67 even during minimally invasive surgery and where the two implants are not in alignment.

In surgery of this type it is sometimes necessary to reposition the implants either during the surgery or in a subsequent surgery. A major advantage of applicant's tools 9 and 10 are that they can be reattached to the bone screw heads 66 by joining of the attachment structure (55 in tool 9) to the mating attachment structure (receiver 78) of a head 66.

VI GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1 through 7 are rejected under U.S.C. 103(a) as being unpatentable over Haider (U.S. Pat. 6,740,098) in view of Roussouly et al. (U.S. Pat. 5,810,816).

VII ARGUMENT-REJECTIONS UNDER 35 U.S.C. 103

The claims stand rejected on obviousness based on a combination of Haider and Roussouly, et al.

The Haider reference is directed to a hook implant wherein the implant has a head with upstanding arms that form a channel therebetween. While the Haider implant is a hook, it is acknowledged that the Hiader structure can be used on a bone screw. It is noted that the Roussouly et al. Reference is cited

for this purpose but other art also exists.

The Haider device includes arms that are longer than necessary for the purpose of capturing the rod and inserting a closure into the channel in the head of the implant. There are grooves along the arms that allow the arms to be broken to reduce the length thereof. As the rejection is understood, the Examiner has taken the position that a portion (A) (page 2 and 3 of action) of the arms is a first guide and advancement structure and that a second portion of each arm (B) is a second guide and advancement structure. While it is seen that arms of the head could be broken into any number of separate sections, this is not seen as disclosing the invention as claimed.

It appears that Haider is designed to be used mainly with open surgery where tools, such as applicant's tools, are not required in order to manipulate and guide the implants from outside the patient's body. Nevertheless, applicant's tools could be adapted to be used in conjunction with the Haider device if attachment structure were added to the Haider device.

Applicant has chosen to extensively discuss Claim 3 which is considered representative of the invention. Claim 3 is directed to a kit for rod implantation. It requires, among other

elements, a plurality of bone screws with each bone screw having a mating attachment structure, a separate guide tool for each bone screw, with each guide tool being non integral relative to a respective bone screw with each guide tool having tool attachment structure to allow it to operably and removably connect with a respective bone screw, and each of the guide tools having first guide and advancement structure that align with guide and advancement structure on the bone screw when the two are joined so as to allow a closure top with mating guide and advancement structure to transfer therebetween under rotation of the closure top.

It is respectfully urged that nothing in Haider teaches, shows or in any way implies a separate and non integral tool that has its own guide and advancement structure for advancing a closure in the tool into the head of the bone screw. Furthermore, the claim calls for mating attachment structure for joining each tool to a respective bone screw. Nothing in Haider shows, teaches or in anyway suggests structure for joining a separate tool to a bone screw head. This joining feature has a definite advantage over Haider in that it allows the tool to be attached, then removed, then reattached, if required by the circumstances of the surgery. Haider provides extensions that once broken away cannot be reattached.

Consequently, it is urged that Haider fails to teach more than one of the elements required in Claim 3. In particular, Haider does not show a separate and non integral tool. Haider does not show attachment structure on a separate tool to attach the tool to a bone screw. Haider does not show attachment structure on a gone screw (or Hook) for attaching to a separate tool. Further Haider does not show guide and advancement structure in a separate tool that aligns with mating guide and advancement structure in the bone screw when the separate tool is attached to the bone screw. Therefore, Haider fails to show the invention either by itself or when taken in combination with any of the art of record and Claim 3 is not obvious in view of a combination of Haider and Roussouly et al. It is noted that the Roussouly references is only peripherally related to the invention and does not teach the elements that are missing from Haider or how to modify Haider to provide the claimed invention.

The remaining Claims call for a tool that is separate or non integral from a rod receiving implant that has separate guide and advancement structure that is designed to align with guide and advancement structure on the rod receiving head. The tools also include attachment structure to allow a surgeon to selectively attach or remove the tool from the head. As noted above, Haider does not in any way teach such structure and it is not taught in

Rousoully, et al.

Claims 8 and 9 stand withdrawn due to a typographical error, because each is dependent from itself. An amendment was submitted to correct this error, but the amendment was not entered. It is believed that Claims 8 and 9 distinguishes over the art of record for the same reasons as Claims 1 to 7 and should be allowable if the dependency is corrected.

VIII CLAIMS APPENDIX

Claim 1 A tool set for implanting a spinal rod in a patient; said tool set comprising:

a) a pair of end guide tools;

b) each of said end guide tool being non integral with and adapted to be selectively joinably attached at a lower end thereof to a respective spinal implant bone screw;

c) each of said end guide tools including a longitudinal guide channel extending upwardly from said lower end thereof; each of said channels being sized and shaped to be adapted to receive opposite ends of the rod for operably guiding the rod ends toward respective bone screws;

d) each of said end guide tools have a helically wound first guide and advancement structure located near a

bottom thereof;

e) said first guide and advancement structure providing a helical pathway adapted to rotatably and matingly receive a mating structure of a bone screw closure top; and

f) said first guide and advancement structure also being adapted to be aligned during joining with a respective bone screw with a second guide and advancement structure on such a respective bone screw so as to continue said helical pathway when a respective guide tool is joined with such a respective bone screw and so as to be adapted to transfer the closure top between a respective guide tool and a respective bone screw upon rotation of the closure top.

Claim 2 An intermediate guide tool for use with a separate spinal implant bone screw; said tool including:

a) lower attachment structure adapted for removable attachment to a respective bone screw;

b) a longitudinal pass through slot extending from a bottom thereof upward and being adapted to receive therethrough and guide the rod to a bone screw attached to said intermediate guide tool;

c) a helically wound first guide and advancement structure located near a bottom of said intermediate guide tool;

d) said first guide and advancement structure providing a helical pathway adapted to rotatably and matingly receive a mating structure of a bone screw closure top; and

e) said first guide and advancement structure also being adapted to be aligned with a second guide and advancement structure on a bone screw so as to continue said helical pathway when said guide tool is attached to a bone screw and so as to be adapted to transfer the closure top between said guide tool and the non integral bone screw upon rotation of the closure top.

Claim 3 A vertebral support rod implantation kit adapted for use with a plurality of vertebra including:

a) a plurality of polyaxial bone screws with each bone screw being adapted for implantation in one vertebra; each of said bone screws having a mating attachment structure;

b) an elongate rod sized and shaped to extend between a pair of end bone screws of said plurality of bone screws;

c) a pair of end guide tools separate from said bone screws;

d) each of said end guide tools being non integral relative to a bone screw and including an end guide

tool attachment structure at a lower end thereof that operably and removably connects with said bone screw mating attachment structure of a respective bone screw;

e) each of said end guide tools including a longitudinal guide channel extending upwardly from near said lower end thereof; each of said channels being sized and shaped to slidingly receive opposite ends of the rod for operably guiding the rod ends toward respective bone screws;

f) each of said end guide tools have a first helically wound guide and advancement structure located near a bottom thereof;

g) said first guide and advancement structure providing a helical pathway adapted to rotatably and matingly receive a mating guide and advancement structure of a bone screw closure top; and

h) said first guide and advancement structure also being operably alignable with a second guide and advancement structure located on a respective bone screw so as to continue said helical pathway when a respective guide tool is selectively joined to a respective bone screw and so as to be adapted to transfer the closure top between a respective guide tool and the bone screw upon rotation of the closure top.

Claim 4 A vertebral support rod implantation kit adapted for use with a plurality of vertebra including:

a) a plurality of polyaxial bone screws with each bone screw being adapted for implantation in one vertebra; each of said bone screws having a mating attachment structure;

b) an elongate rod sized and shaped to extend between a pair of end bone screws of said plurality of bone screws;

c) a pair of end guide tools independent of but selectively joinable with a respective one of said bone screws;

d) each of said end guide tools including an end guide tool attachment structure at a lower end thereof that is non integral with respect to one of said bone screws but that is operably and removably joinable with said bone screw mating attachment structure of a respective bone screw;

e) each of said end guide tools including a longitudinal guide channel extending upwardly from near said lower end thereof; each of said channels being sized and shaped to slidingly receive opposite ends of the rod for operably guiding the rod ends toward respective bone screws;

f) at least one intermediate guide tool having an

intermediate guide tool attachment structure that operably and removably connects with said mating attachment structure of a respective bone screw;

g) each of said intermediate tools including a longitudinal pass through slot extending from the bottom thereof upward and operably receiving therethrough and guiding intermediate locations along the rod to a respective bone screw attached to the intermediate guide tool;

h) each of said end and intermediate guide tools have a first helically wound guide and advancement structure located near a bottom thereof;

I) said first guide and advancement structure providing a helical pathway adapted to rotatably and matingly receive a mating guide and advancement structure of a bone screw closure top; and

j) said first guide and advancement structure also being operably alignable with a second guide and advancement structure located on a respective bone screw when selectively joined thereto so as to continue said helical pathway when a respective guide tool is attached to a respective bone screw and so as to be adapted to transfer the closure top between a respective guide tool and the bone screw upon rotation of the closure top.

Claim 5 The kit according to Claim 3 including:

a) the closure top having the mating guide and advancement structure thereon.

Claim 6 In a guide tool for seating a rod in a spinal implant bone screw and in combination with the bone screw; the improvement comprising:

a) said guide tool being non integral with said bone screw and being selectively operably connectable to said bone screw; said guide tool having a lower first guide and advancement structure;

b) said bone screw having upwardly extending arms forming a rod receiving channel therein and having a second guide and advancement structure;

c) said first and second guide and advancement structures being positioned and aligned when said guide tool is connected to said bone screw so as to form a continuous helically wound path.

Claim 7 The combination of Claim 6 including:

a) a closure top for closing said rod receiving channel between said arms and having thereon a helically wound mating guide and advancement structure that is operably received along said helically wound path upon rotation.

The following two claims stand withdrawn due to a typographical error in the dependency:

Claim 8 The combination according to Claim 8 wherein:

a) said closure top mating guide and advancement structure and said bone screw second guide and advancement structure include interlocking members so as to be interlocking upon being mated.

Claim 9 The combination according to Claim 9 wherein:

a) said first guide and advancement structure has a square thread.

IX EVIDENCE APPENDIX

NONE

X RELATED PROCEEDINGS APPENDIX

NONE

Respectfully submitted,

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Roger P. Jackson
(Applicant)

By _____

December 6, 2006

_____
(Date of Signature)